

### **REMARKS**

Claims 24, 36-39, 41-55, 74, 76-98, and 100-104, have also been rejected under 35 U.S.C. § 112, second paragraph. Applicants again contend that the transitional phrase "consisting essentially of" is not confusing and indefinite and is in fact acceptable in form. See MPEP 2111.03. For the reasons set forth in previous responses by Applicants to this rejection, it is again asserted that the Examiner's view that the transitional phrase "consisting essentially of" should be interpreted as having the same scope as "comprising" is totally without foundation and is merely presumptive on his part.

Claims 1-10, 13, 15-22, 24, 74, and 76-99 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting. Applicants have not filed a Terminal Disclaimer with respect to the claims of copending Patent Application 09/000,604 because no conflicting claims have been patented at this time.

Claims 1-13, 15-24, 36-55, 74, 76-100, and 103-104, have been rejected under 35 U.S.C. § 102(a) as being anticipated by Gregory et al, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Gregory et al in view of Labroo et al.

Gregory et al has been applied as a reference in each of the above rejections under both 35 U.S.C. § 102(a), or, in the alternative, under 35 U.S.C. § 103(a). Applicants traverse both of these rejections and assert that Gregory et al is not a valid reference which can be employed as the basis of either of these rejections.

Applicants' have enclosed herewith the Declaration under 37 C.F.R. 1.131 of Cheryl L. Maslen, Ph.D. ("Dr. Maslen") and of Kenton W. Gregory, M.D. ("Dr. Gregory"). The Declarations of Dr. Maslen and Dr. Gregory establish and confirm completion of the invention in this application, in the United States, at a date prior to May 23, 1996. May 23, 1996, is the

effective date ("Effective Date"), with respect to the above-captioned patent application U.S. Serial No. 08/797,770 ("Application"), of the prior art publication WO 96/14807 to Gregory, et al.

More specifically, Dr. Maslen was, as of the date of execution of her Declaration, an Associate Professor, Molecular & Medical Genetics and Medicine at the Oregon Health & Sciences University ("OHSU") and also Associate Director of the OHSU Heart Research Center, both located in Portland, Oregon. Dr. Maslen conducted tropoelastin research at OHSU in collaboration with Kenton W. Gregory, M.D. and the Oregon Medical Laser Center ("OMLC") in Portland, Oregon. The tropoelastin research conducted in the OHSU laboratory of Dr. Maslen was funded entirely by Dr. Gregory at OMLC. Dr. Maslen clearly states that the work in her laboratory on tropoelastin began on or about September 1995, with the direct participation of Andrew Barofsky, a co-inventor in the above-referenced patent application, was undertaken by Mr. Barofsky, myself, and my laboratory personnel and students. The tropoelastin research, according to Dr. Maslen, was performed in her OHSU laboratory substantially continuously during the period of September 1996 to at least February 7, 1997. Furthermore, the tropoelastin research had continued to the date of execution of Dr. Maslen's Declaration, and beyond, without having been halted or abandoned for other research projects, lack of funding or personnel, or other administrative or financial reasons. Dr. Maslen confirmed that Dr. Gregory has supervised the tropoelastin research in her laboratory since its inception in 1995, and that she has made regular progress reports to Dr. Gregory at OMLC regarding the tropoelastin research. Dr. Maslen's regular progress reports have been included in reports made by Dr. Gregory and OMLC to the research grant sponsor.

The Declaration of Dr. Gregory supports the statements in Dr. Maslen's Declaration. Dr. Gregory's Declaration states that collaborative research was undertaken in Dr. Cheryl Maslen's laboratory at the Oregon Health & Sciences University (OHSU). An initial aim of the

collaboration was to develop a tropoelastin expression system to provide quantities of tropoelastin to the Oregon Medical Laser Center (OMLC) for supporting Dr. Gregory's research at that location. Dr. Gregory substantiates that the work in Dr. Maslen's laboratory on tropoelastin began on or about September 1995, with the direct participation of Andrew Barofsky, a co-inventor in the present patent application, that work having been undertaken by Mr. Barofsky, Dr. Maslen and Dr. Maslen's laboratory personnel and students. Dr. Gregory goes on to state that the tropoelastin research was performed in Dr. Maslen's OHSU laboratory substantially continuously during the period of September, 1996 to at least February 7, 1997 and, in fact, that this research has continued to date of execution of his Declaration. Dr. Gregory also verifies the fact that the tropoelastin research conducted in Dr. Maslen's OHSU laboratory was funded entirely by my research grant for tropoelastin. Finally, Dr. Gregory states that he has supervised the tropoelastin research in Dr. Maslen's laboratory since its inception in 1995, and that he has received regular progress reports from Dr. Maslen regarding this tropoelastin research. These regular progress reports from Dr. Maslen have been included in reports made by Dr. Gregory to the research sponsor.

The lack of applicability of the Labroo et al reference has been discussed in detail in prior responses filed on behalf of Applicants. Therefore, no further discussions of that reference will be forthcoming at this time.

Claims 47 and 48 have been rejected under 35 U.S.C. § 102 (b) as being anticipated by Bedell-Hogan et al. In order to have anticipation under 35 USC Section 102 (b), every element of the claim must be found in the prior art reference. Claims 47 and 48, as stated in prior response to this rejection, include the step of forming a biomaterial consisting essentially of tropoelastin which is not described in the Bedell-Hogan et al reference. Therefore, the above rejection does not constitute prima facie anticipation under 35 U.S.C. § 102 (b).

Claims 47, 48, and 53-55 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Labroo et al. As previously stated, Labroo et al relates to polypeptide materials.

As stated in prior responses to this rejection, Labroo et al does not disclose, suggest or teach a biomaterial consisting essentially of tropoelastin. Therefore, the requirements for a prima facie case of anticipation have not been met with respect to the rejection of claims 47, 48, and 53-55 as being anticipated by the Labroo et al reference.

Claims 101 and 102 have been indicated by the Examiner to be allowable if the rejection under 35 U.S.C § 112, second paragraph, were overcome. Applicants believe that this rejection has been overcome. Claim 101 has previously been rewritten in independent form, and claim 102 is dependent from claim 101.

In light of the above arguments, it is requested that the Examiner reconsider his rejections and pass this case to issue. If, however, the Examiner still believes that has not responded to all of the rejections presently outstanding, he is encouraged to call the Attorney for the Applicants at the telephone number below to discuss same.

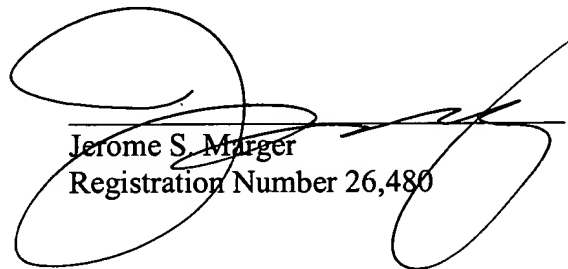
Respectfully submitted,



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